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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,399	02/17/2004	Galla Chandra Rao	IMMC 308 PCT/US	1615

27777 7590 10/13/2009

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
10/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,399	RAO ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE filed 8/3/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-46 and 48-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-46 and 48-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 3, 2009 has been entered.

Amendment Entry

2. Applicant's amendment and response filed August 3, 2009 is acknowledged and have been entered. Claims 44, 53, and 59 have been amended. Claim 47 has been cancelled. Accordingly, claims 44-46 and 48-61 are pending and are under examination.

Withdrawn Rejections / Objections

3. All rejections or objections not reiterated herein, have been withdrawn.

4. The rejections of claim 47 are now moot in light of Applicant's cancellation of the claim.

5. In light of Applicant's amendment and arguments, the rejection of claims 44-46, 48, 49, 53-55, and 57-61 under 35 U.S.C. 102(e) as being anticipated by Fodstad et al. (US Patent 6,265,229), is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 44-46 and 48-58 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44, step c) is vague and indefinite in relation to step b) in reciting, "exposing said colloidal magnetic particles to an externally-applied high gradient magnetic field" because it is unclear as to whether the recited "colloidal magnetic particles" in the instant step comprises those that are coupled to a first biospecific ligand which have reacted to the intact malignant cells and the fragments and debris thereof. Additionally, it is unclear as to whether the term "reacted" as used in the claim intends a binding interaction so as to result to a complex comprising colloidal magnetic particles-first biospecific ligand-intact malignant cell complexes, that are separated as a fraction via exposure to high gradient magnetic field (HGMF). Accordingly, it is unclear as to what is encompassed in the recitation of "substantial exclusion of other specimen components" which appears to include the intact malignant cells, fragments, and debris thereof.

Claim 44, step d) is also confusing in lacking clear antecedent basis in reciting, “contacting said sample having magnetically-labeled said intact malignant cells … with at least one additional biospecific ligand” because it is unclear as to whether it refers back to the sample with magnetically labeled intact malignant cells in step b) or those in question to be bound to colloidal magnetic particles that have been subjected to HGMF in step c). Accordingly, it is unclear as to what is encompassed in the recitation of "substantial exclusion of other specimen components" which appears to include the intact malignant cells, fragments, and debris thereof.

Claim 44, step d) is ambiguous in reciting, “contacting … with at least one additional biospecific ligand” because it is unclear what is intended for the recitation of "the additional biospecific ligand.” Should the additional biospecific ligand be conjugated to a label so as to allow labeling and identification of the intact malignant cells and fragments and debris thereof?

Claim 44, step e) remains vague and indefinite in reciting, “analyzing changes in labeled malignant cells” and “a change in the proportions of said labeled malignant cells” because the term “change” is a subjective term that lacks a comparative basis for defining its metes and bounds, especially as it relates to the term “reacts” as recited in step b). Does Applicant intend morphological, i.e. size, or functional change in the malignant cells as a result of “reaction;” thus resulting to “a change in proportions (size) of the malignant cells” or does Applicant simply intend, “binding interaction” so as to result to a change in amount or numerical proportions of the labeled intact malignant cells and fragments and debris thereof?

Claim 53, step c) is vague and indefinite in relation to step b) in reciting, "exposing said colloidal magnetic particles to an externally-applied high gradient magnetic field" because it is unclear as to whether the recited “colloidal magnetic particles” in the instant step comprises those that are coupled to a first biospecific ligand which have reacted to the intact malignant cells and clusters of malignant cells. Additionally, it is unclear as to whether the term "reacted" as used in the claim intends a binding interaction so as to result to a complex comprising colloidal magnetic particles-first biospecific ligand-intact malignant cell or cluster complexes, that are separated as a fraction via exposure to high gradient magnetic field. Accordingly, it is unclear as to what is encompassed in the recitation of "substantial exclusion of other specimen components" which appears to include the intact malignant cells and clusters of malignant cells.

Claim 53, step d) is also confusing in lacking clear antecedent basis in reciting, “contact[ing] said sample having magnetically-labeled said intact malignant cells … with at least one additional biospecific ligand” because it is unclear as to whether it refers back to the sample with magnetically labeled intact malignant cells in step b) or those in question to be bound to colloidal magnetic particles that have been subjected to HGMF in step c). Accordingly, it is unclear as to what is encompassed in the recitation of "substantial exclusion of other specimen components" which appears to include the intact malignant cells and malignant cell clusters.

Claim 53, step d) is ambiguous in reciting, “contact[ing] … with at least one additional biospecific ligand” because it is unclear what is intended for the recitation of

"the additional biospecific ligand." Should the additional biospecific ligand be conjugated to a label so as to allow labeling and identification of the intact malignant cells and clusters of malignant cells?

Claim 53, step e) remains vague and indefinite in reciting, "analyzing changes in labeled malignant cells" and "a change in the proportions of said labeled malignant cells" because the term "change" is a subjective term that lacks a comparative basis for defining its metes and bounds, especially as it relates to the term "reacts" as recited in step b). Does Applicant intend morphological, i.e. size, or functional change in the malignant cells as a result of "reaction;" thus resulting to "a change in proportions (size) of the malignant cells" or does Applicant simply intend, "binding interaction" so as to result to a change in amount or numerical proportions of the labeled intact malignant cells and clusters of malignant cells?

Claim 56 is indefinite in non-further limiting the recitations in claim 53 from which it depends in reciting, "wherein the magnetic particles are colloidal."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 44-46, 48, 49, and 52-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Terstappen et al. (US Patent 6,365,362).

Terstappen et al. disclose a method of monitoring (staging) malignancy of intact malignant carcinoma cells in a test patient which combines immunomagnetic enrichment, multiparameter flow cytometry, and immunocytochemical analysis to detect, enumerate, and characterize intact malignant carcinoma cells in peripheral blood sample (Abstract; col. 1, lines 11-18; col. 7, lines 7 to col. 8, line 10; and col. 8, lines 53-58). Terstappen et al. teach obtaining a biological mixed cell sample (whole blood sample) suspected of containing intact malignant cells, i.e. rare cells (col. 13, lines 10-13). The mixed cell or blood sample is first contacted with a stabilizing agent (anticoagulant: EDTA) (col. 16, lines 36-37). Thereafter, the mixed cell sample is combined with colloidal magnetic nanoparticles coupled to antibody that specifically binds to a cell surface antigen on the intact malignant cells to form a complex between the colloidal magnetic particles and the intact magnetic cells; hence, magnetically-labeled intact malignant cells. The cell mixture containing the magnetically-labeled intact malignant cells labeled with the colloidal magnetic nanoparticles is exposed to externally-applied high gradient magnetic field (HGMS) so as to exclude or separate unbound components. The resulting fraction of separated magnetically-labeled intact malignant cells is further contacted with antibody-conjugated to a label so as to discriminate and identify other features of the intact malignant cells (col. 8, lines 11-42). The proportion or changes of labeled intact malignant tumor cells is analyzed for any change that occur over time, whereupon change in numbers, i.e. proportions, of intact

malignant cells provides indication of progression of malignancy in the test patient (col. 7, lines 45-56; col. 16, lines 7-29; Table VII; col. 29, lines 12-31). Terstappen et al. specifically teach using colloidal magnetic nanoparticles having a diameter of 90 to 150 nm (less than 200 nm, 90-150 nm) (col. 3, lines 46-52; col. 7, lines 24-42; col. 9, lines 36-43; col. 14, lines 12-30). Terstappen et al. teach that externally-applied HGMS is convenient, simple, and efficient process having the ability to reduce test sample volume (col. 5, line 5 to col. 6, line 21). Terstappen et al. taught that application of externally-applied HGMS on highly magnetic, low non-specific binding colloidal magnetic nanoparticles provides best results for separating rare cell subsets from a mixed cell population (col. 7, lines 7-23). Terstappen et al. also teach incorporating the colloidal magnetic nanoparticles having a diameter of 90-150 nm and coated with a protein base coating into a kit format which further includes a first antibody, a second labeled antibody, and a stain or dye (col. 1, lines 11-18; col. 8, lines 43-53; col. 8, line 66 to col. 9, line 16; col. 18, line 64 to col. 19, line 7; col. 19, lines 36-53). The kit may further include additional antibodies that are specific for different characteristic determinants or cell surface antigens on the intact malignant cells. The kit also includes biological buffer and permeabilization buffer (col. 9, line 35 to col. 10, line 51; Example 9). Terstappen et al. teach classifying the intact malignant cells on the basis of morphologic analysis and epitopic analysis (Example V; Example VII; col. 29, lines 12-31).

In as far as the recitation of cell fragments, cell debris, and cell clusters amongst malignant cells, it appears that so long as the conserved determinants or cell surface

epitopes are present and maintained in the fragments, debris, or clusters in the cell sample along with the malignant cells, for binding to antibody-coated magnetic nanoparticles and antibody-conjugated detectable labels that are specific for the desired conserved epitope common to all intact malignant cells, cell fragments, cell debris, and cell clusters, it would appear that all of the intact malignant cells, cell fragments, cell debris, and malignant cell clusters will be detected and analyzed as to their presence and characterization so as to provide a monitor of malignancy in the test patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terstappen et al. (US Patent 6,365,362) in view of Carbonari et al. (Detection and Characterization of Apoptotic Peripheral Blood Lymphocytes in Human Immunodeficiency Virus Infection and Cancer Chemotherapy by a Novel Flow Immunocytometric Method, Blood 83 (5): 1266-1277 (March 1, 1994)).

Terstappen et al. is discussed supra. Terstappen et al. differ from the instant invention in failing to teach characterizing cell fragments and cellular debris based on their origin as caused by apoptosis or necrosis. Terstappen et al. also does not teach classifying cell fragments and cellular debris based on their origin as caused mechanical damage, drug-induced damage, or immunological damage.

Carbonari et al. teach that non-viable apoptotic lymphocyte cancer cells are present in cancer patient's circulatory system after a high dose of cytotoxic chemotherapy. The cells can be classified into cell fragments and cellular debris which result from apoptosis, necrosis, mechanical damage, drug-induced damage, or immunological damage. Carbonari et al. specifically teach flow cytometrically analyzing, identifying, and quantitating apoptotic cancer cells in unfractionated peripheral blood and immunophenotyping them using labeled monoclonal antibodies. Apoptotic cancer cells are flow cytometrically identified on the basis of peculiar light scatter changes, reflecting their smaller size and their modified nucleus/cytoplasm organization (cell fragments and cellular debris), membrane permeability and decreased cell surface expression of CD45 molecules using FACScan. Based on such criteria, apoptotic cancer cells generated by exposure to ionizing radiation are easily distinguished from

viable or necrotic cells generated by treatment with antibody (immunological damage) and complement (mechanical damage) (Abstract; p. 1268, col. 2 last par.; p. 1269, col. 1 to p. 1271 col. 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Carbonari in detecting and characterizing malignant cell fragments and cellular debris in peripheral blood into the method of Terstappen which isolates and quantitates malignant cells in peripheral blood over time so as to monitor malignancy of cancer cells because Terstappen specifically taught the significance of detecting tumor malignant cells in circulation in the early stage of cancer so as to allow early diagnosis and treatment of the disease and Carbonari specifically taught that cell fragments and cellular debris which result from apoptosis or other causes can likewise be identified, characterized, and immunophenotyped; thus providing accuracy of results in diagnosing and treating cancer malignancy.

9. Claims 44-46, 48, 49, and 52-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitz et al. (US Patent 6,190,870) in view of Liberti et al. (US Patent 5,200,084).

Schmitz et al. disclose an efficient enrichment and detection method and kit for detecting disseminated intact malignant cells in peripheral blood sample comprising a mixed cell population suspected of containing malignant cells (Abstract, col. 1, lines 33-46, col. 2, lines 1-21, and col. 9, lines 43-59). The cells are distant from their site of primary tumor, and their presence amongst hematopoietic blood cells is indicative of

malignancy (metastatic potential) of the tumor or carcinoma cells (col. 1, lines 35-38). The blood sample is treated with stabilizing agent (fixative) prior to performing the enrichment method (col. 1, lines 38-40 and col. 6, line 44 to col. 7, line 4). In practice, the blood sample is mixed with colloidal magnetic nanoparticles having specific antibodies coated thereto, that specifically bind a first determinant, i.e. cytokeratin, present in malignant cells so as to form magnetically-labeled intact malignant cells (column 5, lines 29-41, col. 7, lines 5-22, and col. 8, lines 11-14). The malignant cells comprise cell surface antigens or determinants which are separation markers upon which the antibody-coated magnetic nanoparticles specifically bind or react to (col. 2, lines 33-60). The coated magnetic nanoparticles comprise of a core material (magnetic iron-dextran), protein base polymeric coating (biotin, avidin), and antibody that binds to a characteristic determinant of a malignant cell. The size of the magnetic nanoparticles is within the range of 10 nm to 100 nm, i.e. overlap at 80-100 nm (col. 5, lines 42-67). The sample mixture having magnetically-labeled malignant cells are subjected to high gradient magnetic field to produce separated and enriched malignant cell populations (col. 5, lines 15-19 and lines 49-52, and col. 7, lines 23-64). The cell mixture is further contacted with specific antibodies conjugated to a detectable label that specifically bind a second determinant present in malignant cells. Reagent labels may include a specific agent capable of labeling non-target entities (blocking agent that reduce non-specific labeling). The detectable labels may comprise a panel (cocktail) of antibodies specific for different malignant cell determinants (col. 6, lines 10-35). Thereafter, the antibody-coated magnetic particle – malignant cell – antibody label complexes are analyzed for

the presence of labeled malignant cells, the presence of which provides indication of the presence of malignancy. Analysis of the presence of malignant cells complexed with magnetic particles and detectable labels are performed using flow cytometry, manual cell microscopic analysis, and fluorescent immunocytochemistry microscopic analysis (col. 6, lines 36-43). See also Examples 1-3. The malignant cells may further be characterized as to their phenotype using PCR, ELISA, FISH, chromosome painting, and immunocytochemistry (col. 9, lines 4-15).

In as far as cell fragments, cell debris, and cell clusters amongst malignant cells, it appears that so long as the conserved determinants or cell surface epitopes are present and maintained in the fragments, debris, or clusters in the cell sample along with the malignant cells, for binding to antibody-coated magnetic particles and antibody-conjugated detectable labels that are specific for the desired conserved epitope common to all intact malignant cells, cell fragments, cell debris, and cell clusters, it would appear that all of the intact malignant cells, cell fragments, cell debris, and malignant cell clusters will be detected and analyzed as to their presence and characterization so as to provide a monitor of malignancy in the test patient.

In as far as claims 50-52, Schmitz et al. provide phenotypic characterization of the malignant cells according to fragment length polymorphisms and presence or absence of specific sequences using PCR, ELISA, FISH, and immunocytochemistry (col. 9, lines 4-43).

Schmitz et al. differ from the instant invention in failing to teach externally-applied HGMS.

Liberti et al. teach magnetic separation method for separating cells using colloidal magnetic nanoparticles whereupon an external magnet is applied for producing a magnetic field gradient within the test medium (Abstract; col. 4, lines 22-32; col. 5, lines 4-29; col. 6, lines 21-42). The colloidal magnetic nanoparticles have a diameter of less than 200 nm (col. 6, lines 51-55).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to isolate and enrich the intact malignant cells of Terstappen by HGMS using external magnet as taught by Liberti because Liberti taught that application of externally-applied HGMS on highly magnetic, low non-specific binding colloidal magnetic nanoparticles such as those used by Schmitz provides simple construction and operation of maximized magnetic field gradients which reduce entrapment of non-target cells and eliminate loss of immobilized targeted cells; thus providing best results for separating rare cell subsets from a mixed cell population.

10. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmitz et al. (US Patent 6,190,870) in view of Liberti et al. (US Patent 5,200,084) as applied to claims 44-46, 48, 49, and 52-61 above, and in further view of Carbonari et al. (Blood 83 (5): 1266-1277 (March 1, 1994)).

Schmitz et al. and Liberti et al. are discussed supra.

Schmitz et al. and Liberti et al. differ from the instant invention in failing to teach characterizing cell fragments and cellular debris based on their origin as caused by apoptosis or necrosis. Schmitz et al. and Liberti et al. also do not teach classifying cell

fragments and cellular debris based on their origin as caused mechanical damage, drug-induced damage, or immunological damage.

Carbonari et al. is discussed supra.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the teaching of Carbonari in detecting and characterizing malignant cell fragments and cellular debris in peripheral blood into the method of Schmitz as modified by Liberti which isolates and quantitates malignant cells in peripheral blood over time so as to monitor malignancy of cancer cells because Schmitz recognize the significance of detecting disseminated intact malignant cells in circulation which can be isolated and enriched using the method of Liberti in the early stage of cancer so as to allow early diagnosis and treatment of the disease, and Carbonari specifically taught that cell fragments and cellular debris which result from apoptosis or other causes can likewise be identified, characterized, and immunophenotyped; thus providing accuracy of results in diagnosing and treating cancer malignancy.

Response to Arguments

11. Applicant's arguments with respect to claims 44-46 and 48-61 have been considered but are moot in view of the new grounds of rejection.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

October 8, 2009